MAY 15 2006

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K052290**

Applicant information:

Initial Date Prepared:	August 15, 2005
Name:	**ClearLab PTE, Ltd.**
Address	139, Joo Seng Raod #06-01 Singapore 368362
Contact Person:	Mike Read
Phone number:	Country code 65+ 67491090
Fax number:	Country code 65+ 62848534
Parent Company:	1800 CONTACTS, Inc. 66 E. Wadsworth Park Drive 3rd. Floor Draper, UT 84020
FDA US Agent/ Official Correspondent:	Medvice Consulting, Inc. Martin Dalsing
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**AQUASOFT ALL-DAY & ALL-DAY T (hioxifilcon A) Daily Wear Contact Lens.**

Equivalent Predicate Devices:

The **AQUASOFT ALL-DAY & ALL-DAY T** (hioxifilcon A) Soft Contact Lenses are substantially equivalent to the following predicate devices:

1. **Extreme H_2O** (hioxifilcon A), K992692, Manufactured by Hydrogel Vision Corp.
2. **Benz-G 5X** (hioxifilcon A), K983773, Manufactured by Benz Research & Development
3. **MIERU** (etafilcon A), K030167, manufactured by ClearLab International PTE LTD.

Device Description:

The **AQUASOFT ALL-DAY & ALL-DAY T** (hioxifilcon A) Soft (hydrophilic) Contact Lens is available as a single vision spherical lens, and as a back surface astigmatic (toric) lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (hioxifilcon A) is a random copolymer of 2-hydroxythyl methacrylate and 2,3 –dihydroxypropyl methacrylate, cross linked with ethylene glycol dimethacrylate. It consists of 43% hioxifilcon A and 57% water by weight when immersed in sodium carbonate buffered saline solution. The lens is available clear or with a blue visibility-handling tint, color additive 'Reactive Blue 19', 21 CFR part 73.2121. The United States Adopted Names Council (USAN) has adopted the (hioxifilcon A) name.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 57% water by weight. The physical properties of the lens are:

Refractive Index	1.4058 (wet)
Light Transmission	greater than 95%
Water Content	57 %
Specific Gravity	1.1287 (hydrated)
Oxygen Permeability	20.0×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (Fatt method, ISO 9913-1).

Intended Use:

The **AQUASOFT ALL-DAY (hioxifilcon A) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.
The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

The **AQUASOFT ALL-DAY T (hioxifilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and may have astigmatism of 7.00D of astigmatism or less.
The lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Technological Characteristics:

The technological characteristics of the **AQUASOFT ALL-DAY & ALL-DAY T** contact lens as compared to the technological characteristics of the predicate devices are illustrated on the following page.

Pre-Clinical equivalency / Device	AQUASOFT ALL-DAY & ALL-DAY T (hioxifilcon A) New Device	Extrreme H2O (hioxifilcon A) predicater device	Benz-G 5X (hioxifilcon A) predicater device	MIERU (etafilcon A) predicate device
Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Production Method	Cast-molded	Cast-molded	Lathe-Cut	Cast-molded
FDA Group #	Group # 2 >50% Water, non-ionic Polymer	Group # 2 >50% Water, non-ionic Polymer	Group # 2 >50% Water, non-ionic Polymer	Group # 4 >50% Water, ionic Polymer
USAN name	hioxifilcon A	hioxifilcon A	hioxifilcon A	etafilcon A
Water Uptake(%)	57.0%	61.2%	58.0%	58.0%
Oxygen Permeability (Dk)	20.0 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (Fatt method, ISO 9913-1).	20.5 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	20.2 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	19.9 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
Specific Gravity	1.129	1.118	not measured	1.017

Table #1, Aquasoft All-Day as compared to predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

ClearLab PTE., LTD
c/o Mr. Martin Dalsing
Medvice Consulting, Inc.
2214 Sanford Drive, Suite # B7
Grand Junction, CO 81505

Re: K052290
Trade/Device Name: Aquasoft All-Day® & All-Day T® (hioxifilcon A) Daily Wear Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 2, 2006
Received: May 5, 2006

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K052290

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K052290